K011167

MAY 17 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

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Date:	April 11, 2001

Trade Name:	XSE
Common Names:	Dental adhesive
Classification Names:	Resin Tooth bonding agent ESPE Prompt L-pop
Predicate devices:	Clearfil™ SE bond

XSE self-etching adhesive system is a two-component, light-cured adhesive used for bonding light-cured composites and compomers to tooth structure. The unique aspect of the adhesive system is that it does not require a separate etch to the enamel or dentin prior to applying the adhesive. The adhesive contains an organophosphorous compound that demineralizes the enamel and dentin at the same time that the adhesive components penetrate the tooth. The tooth surface can be lightly air dried or kept slightly moist prior to bonding. The result is a simplified bonding procedure that reduces the potential for sensitivity.

XSE self-etching adhesive system is provided in two-vials or a simplified unit-dose package that is self-contained and allows for the adhesive components to be mixed and dispensed directly out of package.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2001

Ms. Karen O'Malley
Regulatory Specialist
3M Company
3M Center, Building 260-2B-12
Saint Paul, Minnesota 55144

Re: K011167
Trade/Device Name: XSE
Regulation Number: 872.3200
Regulatory Class: II
Product Code: KLE
Dated: April 11, 2001
Received: April 16, 2001

Dear Ms. O'Malley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K011167

Device Name: XSE

Indications for Use:

This device is indicated to direct bonding applications, bonding orthodontic bracket applications, bonding veneers, bonding of pit and fissure sealants to enamel and treatment of hypersensitive roots .

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011167